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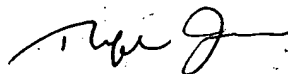
Re: Serial No.: 09/014,076  
Applicants: McGrady, et al.  
For: Method for Tracking and Dispensing Medical Items  
Docket No.: D-1056 Div 3

Sir:

Please find enclosed in triplicate the Brief of Appellants Pursuant To 37 C.F.R. § 1.192 for filing in the above-referenced case.

Please charge the fees associated with this filing (\$310) and any other fees due, to Deposit Account 04-1077.

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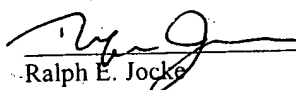
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D-1056 Div 3

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of: <b>R. Michael McGrady, et al.</b>	)	
	)	
Serial No.: <b>09/014,076</b>	)	Art Unit 3651
	)	
Filed: <b>January 27, 1998</b>	)	Patent Examiner:
	)	Michael E. Butler
Title: <b>Method For Tracking And Dispensing Medical Items</b>	)	
	)	

Board of Patent Appeals and Interferences  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**BRIEF OF APPELLANTS PURSUANT TO 37 C.F.R. § 1.192**

Sir:

The Appellants hereby submit their Brief pursuant to 37 C.F.R. § 1.192, in triplicate,  
concerning the above-referenced Application.

**REAL PARTY IN INTEREST**

The Assignee of all right, title and interest to the above-referenced Application is  
Diebold, Incorporated, an Ohio corporation.

## **RELATED APPEALS AND INTERFERENCES**

Appellants believe that there are no related appeals or interferences pertaining to this matter. Page 10 of the Final Action dated November 16, 2000 mentions a confidential patent file which Appellants believe has no relevance to the pending Application. Appellants are also respectfully requesting that these comments be removed from the official file for the reasons later discussed.

## **STATUS OF CLAIMS**

Claims 38-53 are pending in the Application.

Claims 38-41, 43, and 45-53 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Pearson '232.

Claims 48-53 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Pearson '029.

Claims 48-53 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Halvorson.

Claims 39-43, 45-47, and 49-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Pearson '232 in view of Meador et al. ("Meador").

Claims 38-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Pearson '232 in view of Blechl et al. ("Blechl").

Claims 48-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Pearson '029.

Claims 48-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Halvorson.

These rejections were the only rejections present in the Office Action ("Action") dated November 16, 2000. Appellants appeal each claim rejection, inclusive.

### **STATUS OF AMENDMENTS**

A final rejection was made November 16, 2000. No amendments to the claims were requested to be admitted after the final rejection.

### **SUMMARY OF INVENTION**

#### Overview of the Invention

An exemplary embodiment of the invention is directed to a system which is capable of tracking and dispensing medical items, and the method thereof. This system may be used in hospitals and other medical facilities where patients are treated. The system keeps track of which medical items have been used for which patients and assures that sufficient quantities of medical items are maintained on hand for use by patients. The overall system is shown schematically in Figure 13.

The system may include numerous storage locations for medical items. At least one of a particular type of medical item may be stored in each storage location. In many storage locations a plurality of the same type of medical item may be stored. Locations for storing medical items may include storage locations inside a medicine dispenser (100).

The system of the invention further includes display terminals (76, 98, 102). These display terminals may each include a touch screen (78). The touch screen may serve as an input and output device. Through the touch screen a user can receive and input information.

The display terminals are connected through a local area network (LAN) 82 with a computer 84. The computer 84 includes a processor and a data store (page 19, lines 18-20). The data store associated with the computer contains records concerning each storage location, and the type and number of medical items currently stored in the location.

The data store in computer 84 also includes patient records concerning patients in the medical facility for whom medical items may be taken. Data representative of medical items taken for a patient are included in the patient's record.

The data store in a computer (84) also includes user records. The user records contain identifying information associated with authorized users of the system. Authorized users are enabled to operate the display terminals only after they have input data through the display terminal which corresponds to an authorized user record in the data store (Specification page 20, lines 1-4).

The medicine dispenser (100) may operate to dispense only the particular item requested, and not provide access to other items stored in the dispenser. The medicine dispenser 100, as shown in Figure 13, is connected to a display terminal 102, which is connected to the computer.

As shown in Figure 27, the interior of a medicine dispenser (100) includes magazines (168). The magazines, which are shown in greater detail in Figures 14 through 20, are capable of holding vials (170) containing medical items. Each magazine includes a dispensing mechanism which can dispense vials (170) one at a time in response to electrical signals (Specification page 40, lines 9-19). The vials that are released are guided into a pocket 174 in a drawer 176 as shown in Figure 27, from which a user can take the item dispensed. Each magazine has a dispense verification sensor 179 adjacent thereto. The sensor 179 operates to detect the dispense of a vial from the magazine (Specification page 40, line 9 to page 41, line 3).

In the operation of the system, a user inputs appropriate patient information and the desired medications. Furthermore, one or more authorized users may be required to identify themselves at the display terminal 102. In response to the user inputting a dispense instruction, a requested medical item is dispensed from the dispensing device (100) operatively connected to the data terminal. The fact that the medical item has been dispensed from the magazine is verified by sensing the passage of the vial out of the magazine with sensor 179. Upon the dispensed vial being sensed as having been dispensed, the data store's patient record for the identified patient may be updated as well as the inventory record for the location in the dispenser from which the vial was dispensed. The system is also operative to modify the data store to include data representative of the dispense of the medical item by the particular user.

The system of the exemplary embodiment of the present invention provides a fundamental advantage over the prior art by enabling an institution such as a hospital, clinic, or other provider of medical items the capability to securely dispense and track medical items. This system reduces the risk that medical items will be improperly used by tracking the quantity and type of medical items that are actually taken by each user. The system enables identifying activities conducted by users of the system and identification of possible improprieties or patterns of abuse by users.

## **CONCISE STATEMENT OF THE ISSUES PRESENTED FOR REVIEW**

The questions presented in this appeal are:

- ✓ 1). Whether Appellants' claims 38-41, 43, and 45-53 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by Pearson '232.
- ✓ 2). Whether Appellants' claims 48-53 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by Pearson '029.
- 3). Whether Appellants' claims 48-53 are unpatentable under 35 U.S.C. § 102(e) as being anticipated by Halvorson.
- ✓ 4). Whether Appellants' claim 39-43, 45-47, and 49-53 are unpatentable under 35 U.S.C. § 103(a) over Pearson '232 in view of Meador.
- ✓ 5). Whether Appellants' claim 38-53 are unpatentable under 35 U.S.C. § 103(a) over Pearson '232 in view of Blechl.

- 6). Whether Appellants' claim 48-53 are unpatentable under 35 U.S.C. § 103(a) over Pearson '029.
- ✓ 7). Whether Appellants' claim 48-53 are unpatentable under 35 U.S.C. § 103(a) over Halvorson.

## **GROUPING OF CLAIMS**

No groups of claims stand or fall together. Each of Appellant's claims 38-53 recite at least one element, combination of elements, or step not found or suggested in the applied references, which patentably distinguishes the claims.

Every claim recites additional features of the invention which patentably distinguishes the claim over every other pending claim.

The pending claims include three independent claims (claims 38, 48, and 49). Claims 39-43 depend from claim 38. Claims 50-53 depend from claim 49.

The claims involved in this appeal are reproduced in the Appendix.

## **ARGUMENT**

### **The Applicable Legal Standards**

Anticipation pursuant to 35 U.S.C. § 102(b) requires that a single prior art reference contain all the elements of the claimed invention arranged in the manner recited in the claim. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).



Anticipation under 35 U.S.C. § 102(b) requires in a single prior art disclosure, each and every element of the claimed invention in a manner such that the reference would literally infringe the claims at issue if made later in time. *Lewmar Marine, Inc. v. Barient, Inc.*, 822 F.2d 744, 747, 3 USPQ2d 1766, 1768 (Fed. Cir. 1987).

Before a claim may be rejected on the basis of obviousness, the Patent Office bears the burden of establishing that all the recited features of the claim are known in the prior art. This is known as *prima facie obviousness*. To establish *prima facie obviousness*, it must be shown that all the elements and relationships recited in the claim are known in the prior art. MPEP § 2142.

Absent a showing of a teaching, suggestion, or motivation to produce a claimed combination, an obviousness rejection is not proper. *Panduit Corp. v. Denison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593 (Fed. Cir. 1987). *In re Newell*, 891 F.2d 899, 901, 902, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989).

The teaching, suggestion or motivation to combine the features in prior art references must be clearly and particularly identified in such prior art to support a rejection on the basis of obviousness. It is not sufficient to offer a broad range of sources and make conclusory statements. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

It is respectfully submitted that the Action from which this appeal is taken does not meet these burdens.

#### **The Action Is Defective**

Appellants submit that the Action does not comply with the rules of the Patent Office. Nor has the Office properly conducted a *Graham v. John Deere Co.* analysis. Specifically the

Action fails to provide Appellants with an element by element analysis of each claim, and an indication of where the elements or steps in each claim are found in the applied art. On numerous occasions the Action is silent as to which elements, if any, in the applied references constitute the recited features and relationships. Further, the Action fails to identify a source of any teaching, suggestion, or motivation in the prior art to produce the invention as claimed by Appellants. MPEP § 706.02(j). Rather the Action consists of citations to features found in references and parenthetical indications of Appellants' claims which encompass such features. In this way, the Action appears to be an attempt at impermissible reconstruction of Appellants' invention based on Appellants' own teachings. Such analysis is impermissible and does not constitute a valid basis for a finding of obviousness. *In re Fritch*, 22 USPQ2d 1780 (Fed. Cir. 1992).

The Action does not state in any way that is reasonably understandable by Appellants, where the elements recited in Appellants' claims are allegedly found in the applied art. Nor is there any citation to any alleged teaching, suggestion, or motivation to combine features of the prior art references to produce the invention as claimed by Appellants. For this reason it is respectfully submitted that the Action fails to establish a prima facie case of obviousness against any of the claims and the rejections should be withdrawn.

Because the Action fails to apply the references to the claims, Appellants have been forced to speculate as to possible rationales for the rejections. However, the Patent Office bears the burden of citing and applying prior art in a clear manner to support any rejections made. The failure by the Office to indicate the recited claim features in the applied references constitutes

Agency action under the Administrative Procedures Act acknowledging that the references do not meet the recited claim features. Thus, the Action's failure to clearly identify on the record the allegedly recited features in the applied references has been taken as an admission by the Office that the applied references do not disclose or suggest the recited features. It follows that the recited invention would not have been obvious.

Nevertheless, Appellants have reviewed the references cited and have determined that for the reasons stated herein that the cited references, taken individually or as a whole, clearly do not teach or suggest the inventions recited in Appellants' claims. Therefore, the claims directed to the present invention would not have been obvious to one having ordinary skill in the art.

#### **The Pearson '232 Reference**

The reference to Pearson '232 is directed to dispensing medication. The apparatus includes a movable cart (2). The cart includes containers (8) and drawers (10) for holding medications. A suction tube (12), which is handled and operated by a nurse, is used to dispense pills and tablets from the containers (8). The nurse may also manually dispense other medication items (e.g., cream, syringe) from a drawer (10). A computer (14) has an input device such as a keyboard. The computer controls locking of the containers (8) and drawers (10), and monitors operation of the suction tube (12). After medications are loaded into the dispenser, the computer controls access to the individual compartments. The computer may correlate the time and a patient's identity to the dosages of each pill appropriate for that patient at that time in accordance with the medication orders. Thus, each patient's medication is scheduled in advance.

Patient information and physician orders may be input into the computer. The computer then compiles a list of medications needed for a selected period of time. A pharmacist reviews the list and loads the proper quantities of medications into the proper containers and drawers. After the pharmacist confirms to the computer that each medication has been properly loaded, then the cart is ready to be used by a nurse to dispense medications to multiple patients.

During dispenser operations the cart may be rolled to several different patient locations. A nurse enters a password to be authorized to use the medication dispenser. The nurse also inputs patient identifying information. After the nurse verifies the correct patient information, then the preprogrammed computer unlocks each appropriate container (8) or drawer (10) which holds medication which that particular patient is scheduled to receive at that time (col. 5, lines 1-8). A signal light (22) for each unlocked container (8) or drawer (10) may be changed to green, making it easy for the nurse to identify the proper medication compartment. If the medication is in a drawer (10), then the nurse may manually remove it. If the medication is in one of the containers (8), then the nurse uses the suction tube (12) to withdraw the medication. If the medication is in one of the drawers (10), then the nurse manually withdraws the needed item.

### **The Pearson '029 Reference**

The reference to Pearson '029 is directed to dispensing medication. The apparatus includes a movable cart (30). The cart includes drawers (22), cubicles (8), and a dispenser mechanism (35) having upwardly open containers (37) for holding medications. A suction tube (104), which is handled and operated by the computer-controlled mechanism, is used to dispense

tablets from the containers (37). A nurse may manually dispense other medication items from the drawers (22) and the cubicles (8).

In operation, with the cart properly loaded with medications, the nurse inputs a patient's identifying data into the computer keyboard (14). The computer includes a software program which acts on the inputted patient identifying data. The computer acts to energize a lamp (23, 27, 117) corresponding to a particular drawer, cubicle, or container for the medication for the identified patient. The nurse can then identify the medication location using the lamp and manually remove the accessible medication. If the medication is a tablet in one of the containers (37), then the computer can activate and control the mechanical mechanism to dispense the proper medication at an accessible location (120) for the nurse.

### **The Halvorson Reference**

Halvorson discloses a system for dispensing medications in a health care institution. The disclosure of Halvorson is incomprehensible due to lack of important details concerning operation of the system. Due to Halvorson's lack of a disclosed operation, Appellants have been required to speculate as to how the Halvorson system could be made to operate. Therefore, the description of Halvorson herein shall not be construed as agreement or an admission by Appellants that the Halvorson system is capable of operation or of achieving any of the functions carried out by Appellants' system.

Halvorson appears to have a central computer (10) that includes files related to patients and medications prescribed for those patients. No medication can be dispensed without first

being authorized by a physician (col. 4, lines 31-32). The files concerning the prescribed medication orders for the patients are input into the central computer at a pharmacy, and appear to include the times at which medications are to be administered. Software in the computer controls the dispensers to dispense medications according to the orders specified (Abstract lines 4-7). Hence, a medication cannot be dispensed from the Halvorson system for a patient unless a specific instruction to dispense that medication from a particular dispenser at a particular time is first input into the system (col. 12, lines 52-54; col. 3, lines 47-49, 60-63; Abstract lines 4-7). Halvorson also states that the database files include information on where medications are stored, and Halvorson allocates the medications in storage to the particular patients who will receive them from the particular dispenser in the future (col. 4, lines 40-46). Thus, each patient's medication is scheduled in advance.

Halvorson describes dispenser terminals which hold medications. Electro-mechanical dispensers (32) are connected via communication lines to the central computer and are responsive to control signals from the computer to automatically dispense the scheduled medications. The dispensers have electrical interfaces that receive data from the central computer relating to the dispensing of medication to nurses (col. 3, lines 47-51). A printer is positioned at each dispenser terminal. Every hour the central computer causes a printout to be generated on the printer at each dispenser terminal. The printout is a list of patients and the medications that are to be given to those patients at that time (col. 4, lines 56-60). The patients that are listed on the printout at the dispenser are those patients that have been assigned to that dispenser by the system, and for whom medications have been reserved in the dispenser.

Scheduled medications listed in the computer program are automatically dispensed by the dispenser via the central computer.

Although no explanation of how it could be done is provided, Halvorson also discusses using his system in circumstances where nurses take medications from storage areas that do not have dispensers, e.g., a floor cart (col. 5, lines 36-50). It is assumed that at these storage areas periodic reports are printed that list patients and the medications from the storage areas that these listed patients are to receive. It appears that a nurse manually takes a medical item from a storage area then inputs the item information into the host computer (in a manner not explained).

Halvorson states that his host computer has a database. Halvorson states that his database includes a personnel master file which includes a “password” for each employee (col. 11, line 15). However there is no statement or suggestion in Halvorson as to what use (if any) is made of such stored passwords. Nor does it appear that Halvorson has any teaching or suggestion that information concerning the identity of the particular nurse who actually takes the dispensed medical items is ever recorded in the database.

### **The Meador Reference**

The reference to Meador is directed to a medication storage and retrieval system. A tray (108) includes compartments (112) having lids (114). Each compartment (112) includes a specific pharmaceutical item. Each lid (114) has associated therewith a mechanism responsive to signals from a computer (106) to permit lid movement between open and closed positions.

### **The Blechl Reference**

The reference to Blechl is directed to a drug dispensing apparatus (Figure 2). This dispenser device has a user interface screen in communication with a computer (col. 3, lines 20-26). This screen is touch sensitive for inputting commands into the computer. The dispenser also includes a card reader for reading a magnetic user identification card (col. 27-31).

Blechl states that when a user desires medication, the user initiates dispensing by inserting an identification card into the card reader, upon which the computer of the dispenser requests the user to input a personal identification number (PIN). Upon entering this PIN via the touch screen, the computer compares this entered PIN to the card. If there is a match, the user has access to the dispenser (col. 3, lines 37-47).

### **Pearson '232 and Meador Do Not Constitute Prior Art**

The Action on page 10 indicates that the 37 CFR § 1.131 Declaration (filed August 30, 2000) was accepted and entered by the Office. The Action further indicates that the Declaration removes Meador as a reference with respect to claims 38 and 48. However, the Action maintains that Pearson '232 is entitled to the filing date of Pearson '029 (which is earlier than the March 7, 1994 date sworn behind in the Declaration). The Appellants disagree.

### **Pearson '232 Does Not Constitute Prior Art**

As acknowledged in the Action, this Application is a divisional of U.S. Patent Application Serial Number 08/361,783 filed December 16, 1994. As the Patent Office has



verified, each and every feature of the pending claims is disclosed in the prior parent patent application having this filing date. In addition, numerous elements of pending claims are disclosed in earlier applications from which this Application claims priority, including Application Serial Number 08/009,055 filed January 25, 1993 (now U.S. Patent 5,404,384) and Serial Number 08/186,285 filed January 25, 1994 (now U.S. Patent 5,533,079).

The filing date of the Pearson '232 reference is February 12, 1996. This date is almost fourteen months after Appellants' priority date of December 16, 1994. Pearson '232 claims priority of several earlier applications. Pearson '232 is a continuation of Pearson 5,490,610, which is a continuation of abandoned Application Serial Number 206,877, which a continuation-in-part (CIP) of Pearson '029.

However, Pearson '232 can claim a priority date no earlier than March 7, 1994, which is the filing date of Application Serial Number 206,877. This is because Application 206,877 is a CIP of Pearson 029. Thus, March 7, 1994 is the date in which Application 206,877 (and Pearson '232) relied on new subject matter (not found in Pearson '029) to support the invention therein. This new matter was critical to the issued Pearson '232. Thus, at best, March 7, 1994 is the critical reference date of Pearson '232.

Furthermore, when a patent is used to reject claims under 35 U.S.C. § 102(e), the disclosure relied on in the rejection must be present in the issued patent. Subject matter which is disclosed in a parent Application (Pearson '029) but not included in the child CIP (Pearson '232) cannot be relied on in a 35 U.S.C. § 102(e) rejection applying the issued CIP. It is respectfully submitted that this is the current situation. Pearson '232, being the CIP of Pearson '029, lacks

large amounts of subject matter that was disclosed in the great-grandparent Pearson '029. Thus, Pearson '232 is not entitled to the "missing" subject matter that was not carried over from Pearson '029.

An example of this "missing" subject matter from Pearson '029 is the mechanical dispenser (35) which obtains medication from an onboard supply and then dispenses it to a specific location. In Pearson '232 the dispensing operation is manually done by hand instead of a dispenser mechanism. Thus, Pearson '232 is not entitled to prior subject matter relating to a dispenser mechanism.

Furthermore, while Pearson '232 also claims priority to applications (e.g., Pearson '029) earlier than March 7, 1994, these earlier applications do not disclose the subject matter which made Pearson '232 patentable. This is demonstrated by Pearson '029 which has been cited in the Action. As evidenced by the Action itself, Pearson '029 does not disclose the features that were considered pertinent to pending claims (e.g., claim 38). As a result, at best the earliest date which Pearson '232 may claim for the disclosure in Pearson '232 is March 7, 1994, which is considerably less than one year prior to Appellants' filing date.

Additionally, the Declaration of Applicant, R. Michael McGrady, submitted on behalf of the Assignee of the present invention, was accepted and entered by the Office. Appellants reduced their invention claimed in at least claims 38 and 48 prior to March 7, 1994. This fact is shown through the entered Declaration. The entered Declaration and corroborating documentation proved that Appellants reduced their invention to practice in this country prior to

the earliest possible effective filing date of the Pearson '232 patent. As a result, Pearson '232 does not qualify as a reference against each of Appellants' claims.

Additionally, the entered Declaration and documentation established that prior to the effective filing date of the Pearson '232, Appellants reduced to practice in this country an invention which would serve to render the invention, as claimed in at least claims 38 and 48 of the pending Application, obvious to one having ordinary skill in the art. This further obviated the effect of Pearson '232 as a prior art reference against Appellants' claims.

As the evidence of record establishes that Appellants reduced their invention to practice in this country prior to the earliest possible effective filing date of Pearson '232, the Pearson '232 patent cannot be properly applied as a reference against each of the pending claims. Therefore, the Pearson '232 patent cannot be properly applied as a reference against at least claims 38 and 48. As a result, the rejections of at least claims 38-48 involving Pearson '232 are obviated. Thus, Pearson 232 does not constitute prior art in the instant application. It is therefore respectfully submitted that the rejections which rely on the Pearson '232 reference have been overcome.

Furthermore, because Pearson '232 does not constitute prior art in the instant application, Appellants find it unnecessary to discuss in this Brief the detailed reasons why Pearson '232 does not anticipate or render obvious the features and relationships recited in the claims against which it was cited in the Action. Nevertheless, Appellants show hereinafter that the appealed claims patentably distinguish over the Pearson '232 reference.

### **Meador Does Not Constitute Prior Art**

As acknowledged in the Action, this Application is a divisional of U.S. Patent Application Serial Number 08/361,783 filed December 16, 1994. As the Patent Office has verified, each and every feature of the pending claims is disclosed in the prior parent patent application having this filing date. In addition, numerous elements of pending claims are disclosed in earlier applications from which this Application claims priority, including Application Serial Number 08/009,055 filed January 25, 1993 (now U.S. Patent 5,404,384) and Serial Number 08/186,285 filed January 25, 1994 (now U.S. Patent 5,533,079).

The filing date of the Meador reference is October 2, 1996. This date is almost twenty-two months after Appellants' priority date of December 16, 1994. Meador is a continuation of abandoned Application Serial Number 314,325, filed on September 28, 1994. Hence, Meador can claim a priority date no earlier than September 28, 1994.

Additionally, the Declaration of Applicant, R. Michael McGrady, submitted on behalf of the Assignee of the present invention, was accepted and entered by the Office. Appellants reduced their invention to practice prior to March 7, 1994. This fact is shown through the entered Declaration. Hence, the evidence of record establishes that Appellants reduced their invention to practice in this country prior to the earliest possible effective filing date (September 28, 1994) of Meador. Therefore, the Meador patent cannot be properly applied as a reference against at least claims 38 and 48. As a result, the rejections of at least claims 39-43 and 45-47 involving Meador are obviated. Thus, the Meador reference does not constitute prior art in the

instant application. It is therefore respectfully submitted that the rejections which rely on the Meador reference have been overcome.

**Obviousness Type Rejections Based on Either Pearson '232 or Meador Are Overcome**

The Patent Office Rules provide that when an obviousness rejection is based on one or more references and the applicant swears behind one reference, then the obviousness rejection is overcome. MPEP § 715.02. Appellants have actually sworn behind both Pearson '232 and Meador. As a result, the rejection of at least claims 39-43 and 45-47 as obvious over Pearson '232 in view of Meador is obviated. Also, the rejection of at least claims 38-48 as obvious over Pearson '232 in view of Blechl is obviated.

Furthermore, the Action on page 10 admits that the Declaration "is effective in overcoming the rejections relying upon" "the Meador reference with respect to claims 38 and 48." However, it is noted that claims 39-43 and 45-47 depend from claim 38. Hence, Meador is admittedly not prior art against at least claims 38-43, 45-47, and 48.

Additionally, the Office inherently admits that the Declaration has established that Appellants reduced their invention of at least claims 38 and 48 to practice prior to March 7, 1994.

**(iii) 35 U.S.C. § 102**

Appellants' arguments against the prior art rejections are based on the Office's interpretation of the reference as indicated and applied in the Action. Therefore, it is respectfully

submitted that any other interpretation of the reference by the Office would constitute a new grounds of rejection.

### **The Pending Claims Are Not Anticipated By Pearson ‘232**

Claims 38-41, 43, and 45-53 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Pearson ‘232.

These rejections are respectfully traversed. Appellants traverse these rejections on the grounds that the Pearson ‘232 reference does not contain all the elements of the claimed invention arranged in the manner recited in the claims. The features recited in Appellants’ claims patentably distinguish over the Pearson ‘232 reference.

Appellants also traverse these rejections on the grounds that the Pearson ‘232 reference does not constitute prior art.

#### **Claim 38**

Claim 38 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites “removing one unit of a type medical item from a storage location with a dispenser mechanism.”

Appellants respectfully submit that Pearson ‘232 does not disclose the recited features and relationships. The Action alleges that Pearson ‘232 discloses the recited “removing” step at col. 5, line 42 to col. 6, line 2, and at col. 5, lines 9-35. However, Pearson ‘232 does not disclose the recited “removing” step at the cited sections of Pearson ‘232. The cited sections refer to a nurse manually removing a medical item using a suction tube (12). However, claim 38 recites

that it is a dispenser mechanism which carries out the “removing” of a medical item from its storage location, not a human hand. All of the embodiments in Pearson ‘232 involve a nurse manually removing a medical item from its storage location.

Pearson ‘232 at col. 5, lines 9-11 clearly states “the nurse inserts suction tube 12 into the corresponding orifice tube 24.” That is, in Pearson ‘232 a nurse performs the “removing”, not a mechanism. Pearson ‘232 actually works opposite to the recited invention and requires physical labor on the part of the nurse to remove a medical item from its storage location. Pearson ‘232 lacks a “dispenser mechanism.”

It is well known that a mechanism implies mechanical operation, not human hand operation. Therefore, mechanism operation is distinguished from hand operation. Thus, a nurse cannot constitute the recited “dispenser mechanism.” Furthermore, the suction tube (12) of Pearson ‘232 is merely a tool or instrument to be used by the nurse, it is not part of nor does it constitute a dispensing mechanism. Again, in Pearson ‘232 it is the nurse that performs the dispensing. The suction tube (12) alone cannot perform any dispensing. Nor is the suction tube (12) used with a “dispenser mechanism” to perform the removing step.

Furthermore, Appellants’ disclosure makes clear that the recited “dispenser mechanism” relates to mechanical operation and not human hand operation. For example, “Each magazine 168 includes a vial dispensing mechanism later described in detail that releases vials in response to electrical signals one at a time from the lower end of the magazine” (Specification page 40, lines 16-18). “The operation of the vial dispensing mechanism is shown in greater detail in

Figures 10 through 22” (Specification page 41, lines 16-17). “The actuating mechanism for the front and back gates is shown in Figures 17 through 22” (Specification page 44, line 3).

Furthermore, Appellants’ disclosure states that “The vial dispensing mechanism of the present invention enables the controlled dispense of one vial at a time from the magazine in response to an electrical signal. This assures that only the requested medication is dispensed.” “In addition, the gate members are suitably secure so as to avoid tampering by persons who might attempt to gain access to the interior of the medicine dispenser 100 through the dispenser drawer 176.” (Specification page 45, lines 6-12). Thus, the recited dispensing mechanism of claim 38 actually prevents access to the medical items by a human hand to prevent tampering. Contrarily, Pearson ‘232 allows access to the pills by hand which could lead to tampering. Thus, the recited invention of claim 38 is a clear improvement over the Pearson ‘232 reference.

As previously discussed, Pearson ‘232 does not disclose the recited step of “removing one unit of a type medical item from a storage location with a dispenser mechanism.”

Claim 38 recites “removing one unit of a type medical item from a storage location with a dispenser mechanism.” Claim 38 further recites that “the data store is modified responsive to the removing step and the inputting step, to include data representative of the dispense of the type medical item.” There is no indication that in Pearson ‘232 data is modified responsive to actually removing a type medical item from a storage location with a dispenser mechanism. There is no indication that in Pearson ‘232 “data is modified” based upon the dispense of a type medical item.



Pearson '232 is not capable of verifying that a medical item was actually removed with a dispenser mechanism. In Pearson '232 the sensors (42) are used to detect the presence of a pill. Upon the sensor detecting a pill, the computer is then updated to reflect (assumed) removal of a pill in order to keep accurate inventory (col. 5, lines 29-33). However, the sensors (42) only detect whether a pill, while still in the container, has been successfully picked up. The sensors (42) do not verify whether a pill was actually dispensed. A data store is not modified responsive to actually removing a type medical item, as is specifically recited.

For example, Pearson '232 at col. 6, lines 8-10 indicates that the pill may be accidentally dropped. That is, a pill may be dropped after the pill was detected by the sensors (42). Hence, the detected pill may be dropped (e.g., in the same container) without ever being dispensed or reaching the patient. Thus, Pearson '232 is not capable of verifying an actual medical item removal from a storage location with a dispenser mechanism. Therefore, inaccurate data may be presented. Thus, the claimed invention is an improvement over the Pearson '232 reference.

Pearson '232 does not disclose “modifying data” in a data store responsive to actually removing a type medical item from a dispenser mechanism. That is, Pearson '232 does not disclose modifying data indicating that the requested medical item was actually dispensed. Therefore, Pearson '232 does not disclose the recited steps of “removing” or “modifying.”

In an exemplary embodiment of the present invention there is a verification that the item actually dispensed is that item that is recorded for that particular patient (Specification page 45, line 13 to page 46, line 2). That is, in the exemplary embodiment the dispense of any item from a location and the provision of such item to a patient is only recorded in the computer data store

after the dispense is verified by a sensor (e.g., 179) (Specification page 40, lines 1-3) associated with the magazine. This permits the assurance that the requested medical item has been truly dispensed by the dispenser mechanism. A dispense verification sensor may be used to minimize the risk that a dispense will be recorded which has not actually occurred due to a malfunction. Pearson '232 provides no disclosure that a medication has been actually verified as having been dispensed prior to indicating such in a data store. The Pearson '232 reference appears unconcerned about the possibility of inaccurately recording a particular medical item when the item was never actually dispensed. In Pearson '232 the dispensing of a medical item is recorded whether or not it actually occurred. Therefore, the system of Pearson '232 permits medication errors to occur. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed to a user (e.g., nurse). Pearson '232 has none of these advantages. Thus, the invention recited in claim 38 is clearly an improvement over the Pearson '232 reference.

It follows that there is no indication that Pearson '232 is responsive to the completion of the inputting and removing steps to modify a data store in the manner recited. Furthermore, there is no indication in Pearson '232 that a data store is modified to include data representative of the actual "dispense of the type medical item for the patient." Pearson '232 is not directed to having data modified in response to both inputting patient identifying data and removing (dispensing) a medical item with a dispenser mechanism. Nor is Pearson '232 directed to modifying a data

store to include data representative that the medical item was actually dispensed for that particular patient.

Furthermore, claim 38 refers to different “types” of medical items, and removing a particular “type” of medical item. The “modifying a data store” is “responsive to the removing” of a particular “type” of medical item. Pearson ‘232 is not directed to modifying a data store to include data representative that the medical item was verified as a particular “type” of medical item. There is no indication in Pearson ‘232 that a particular “type” of medical item is ever confirmed as actually having been dispensed from a dispenser mechanism.

It follows that Pearson ‘232 does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection. Hence, Appellants’ claim 38 patentably distinguishes over the Pearson ‘232 reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn. It follows that the claims which depend from claim 38 are likewise allowable.

#### **Claim 39**

Claim 39 depends from claim 38 and further recites that “the data store further includes data representative of a plurality of authorized users.” The claim further recites “the processor operatively controls the dispenser device to enable performance of the removing step only when the input user identifying data corresponds to an authorized user.” The claim further recites “determining with the processor whether the input user identifying data corresponds to data for an authorized user stored in the data store.”

As previously discussed, Pearson '232 does not disclose the recited dispenser device. Furthermore, Pearson '232 also does not disclose a "processor" with the capability to control the "dispenser device to enable performance of the removing step." In Pearson '232 the nurse does not constitute a "dispenser device" or a "processor" in the manner recited.

Furthermore, there is no indication in Pearson '232 that the nurse's inputted password corresponds to data for an authorized user stored in the data store, wherein the data store includes data representing a plurality of authorized users. The "password" arrangement and operation in Pearson '232 is not discussed. The Action has wrongly assumed (based on hindsight of Appellants' invention) that an individual nurse's password, along with other passwords, is stored in a data file in the computer, then when that nurse provides a password it is compared with the passwords in the computer data file. However, Pearson '232 does not disclose such action.

Pearson '232 does not disclose a computer associated with a data store having stored user information corresponding to plural "authorized users." Further, Pearson '232 does not have a computer that operates responsive to the input of identification data that corresponds to one of the authorized users. Pearson '232 operates to dispense medication in the manner expressly indicated therein (e.g., col. 4, line 60 to col. 5, line 5). First a password is entered (via a keyboard; col. 3, lines 13-15) by a nurse to authorize use of the dispenser. Next the nurse enters patient identification information. Next the nurse verifies that the screen displayed by the computer corresponds to the correct patient. Then the computer unlocks each container (8) or drawer (10) holding medication that the patient is scheduled to receive at that time.

During an unscheduled request (e.g., an emergency) the dispensing of medication may also occur (col. 6, lines 6-23). However, the acting nurse has to provide their name and an explanation for the reason of the request. The computer is able to record all pertinent information, including the medications dispensed, the amount of medication, the identity of the patient, the time dispensed, the name of the nurse, and the explanation.

Pearson '232 does not disclose a computer in operative connection with a data store, which data store includes data for a plurality of authorized users. The device of Pearson '232 requires the user to input a password. However, there is no indication in Pearson '232 that the nurse's inputted password corresponds to data for an authorized user stored in the data store, wherein the data store includes data representing a plurality of authorized users.

It is unclear whether the password arrangement of Pearson '232 is directed to be a multi-user password which enables several different persons to access the dispenser using the same single password (similar to a personal computer), or whether the inputted password is matched with a password stored in a data file on a card (like some ATM cards). Thus, if the arrangement of Pearson '232 is similar to a personal computer then only a single password is required, and any nurse that has been authorized to know the current password may access the medication dispenser. However, if this were the situation, then Pearson '232 would have no need of a data store having "data representing a plurality of authorized users", but merely the storage of a single password.

Furthermore, if the arrangement of Pearson '232 uses an identification card, then the inputted password would be matched with the password stored in a data file on the card (like

some ATM cards). A computer would determine whether the passwords matched. However, the card's data store would not constitute the "data store" (which also includes patient and medical item data) recited in claim 38.

It follows that Pearson '232 does not disclose a computer associated with a data store having stored user information corresponding to an "authorized user." Pearson '232 does not disclose that a computer operates in response to determining that the inputted user identification data corresponds to one of a plurality of different authorized users. Pearson '232 does not disclose in any manner that a plurality of different passwords are required. Nor does Pearson '232 disclose that a plurality of different passwords are required corresponding to different authorized users. Nor does Pearson '232 disclose that the plurality of different passwords are stored in a data store, where the passwords reflect data representative of a plurality of authorized users. Pearson '232 does not disclose a plurality of authorized users' data stored in a data store. Nor does Pearson '232 disclose a computer in operative connection with the data store. Nor does Pearson '232 disclose comparing (corresponding) inputted identification data with that of a plurality of authorized users' data. That is, in Pearson '232 there is no disclosure or suggestion of comparing a password to a plurality of authorized passwords in a data store.

Since Pearson '232 does not indicate that a nurse's "identifying data" (password) corresponds to one of a plurality of authorized users' data in a data store (which also includes patient and medical item data), then the claim cannot be anticipated. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 40**

Claim 40 depends from claim 39 and further recites that in the modifying step, the data store is further modified to include data representative of a record that the authorized user, determined in the determining step, actually dispensed the type medical item.

In Pearson '232 the sensors (42) are used to detect the presence of a pill. However, the sensors (42) only detect whether a pill, while still in the container, has been successfully picked up. Pearson '232 does not determine whether a pill was actually dispensed. For example, col. 6, lines 8-10 indicates that the pill may be accidentally dropped. That is, a pill may be dropped after the pill was detected by the sensors (42). Hence, the detected pill may be dropped (e.g., in the same container or on the floor) without ever being dispensed or reaching the patient. Thus, Pearson '232 is not capable of verifying an actual dispensing. Therefore, Pearson '232 is not capable of producing an accurate record that the medical item was actually dispensed in the manner intended. Therefore, Pearson '232 is not capable of producing an accurate "record that the authorized user . . . dispensed the type medical item." Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 41**

Claim 41 depends from claim 39 and further recites determining with the processor whether the input user identifying data corresponds to two different authorized users. The claim recites that the removing step is enabled to be performed only after the data received corresponds to two different authorized users. That is, the identifying data input of two different authorized

users is required prior to the step of “removing one unit of a type medical item from a storage location with a dispenser mechanism” being permitted.

Pearson ‘232 does not disclose requiring identifying data from two different authorized users. Therefore, Pearson ‘232 cannot anticipate the claim. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 43**

Claim 43 depends from claim 38 and further recites “sensing with a verification sensor the dispense of the type medical item removed in the removing step, wherein the verification sensor is in operative connection with the processor, and wherein the modifying step is not performed if the dispense of the item is not sensed in the sensing step by the verification sensor in the sensing step.”

As previously discussed, in Pearson ‘232 the sensors (42) are used to detect the presence of a pill. However, the sensors (42) only detect whether a pill, while still in the container, has been successfully picked up. In Pearson ‘232 the sensors (42) do not verify whether a pill was actually dispensed. Therefore, inaccurate data may be presented. Thus, the claimed invention is an improvement over the Pearson ‘232 reference.

For example, Pearson ‘232 at col. 6, lines 8-10 indicates that the pill may be accidentally dropped. That is, a pill may be dropped after the pill was detected by the sensors (42). Hence, the detected pill may be dropped (e.g., in the same container or on the floor) without ever being dispensed or reaching the patient. Thus, Pearson ‘232 is not capable of verifying an actual medical item dispensing. Therefore, Pearson ‘232 does not disclose a “verification sensor” in the



manner recited, but merely a “picked up” sensor. It follows that Pearson ‘232 is not capable of “sensing with a verification sensor the dispense of the type medical item removed in the removing step.” Nor is Pearson ‘232 capable of not performing a modifying step “if the dispense of the item is not sensed in the sensing step by the verification sensor.” Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 45**

Claim 45 depends from claim 38 and further recites that “the removing step includes opening an electronic lock drawer.”

As previously discussed, Pearson ‘232 does not disclose the recited dispenser device. It follows that Pearson ‘232 does not disclose the recited “removing step.” It further follows that Pearson ‘232 does not disclose “opening an electronic lock drawer” in the “removing step.” Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 46**

Claim 46 depends from claim 38 and further recites that “the removing step includes releasing one container from a magazine holding a plurality of containers.” In an exemplary embodiment of the invention (e.g., Figure 14) a dispenser magazine (168) holds a plurality of vials (170).

The alleged “removing step” of Pearson ‘232, which includes using a suction tube (12), is limited to handling a pill in a container (8). The pill does not constitute a “container.” Nor is the suction tube (12) of Pearson ‘232 capable of handling a container. Nor is the container (8) “released” from a magazine. Pearson ‘232 does not disclose a “container” in the manner recited;

nor does Pearson '232 disclose a "magazine holding a plurality of containers"; nor is Pearson '232 capable of "releasing one container from a magazine" in the manner recited.

It follows that Pearson '232 does not disclose the recited "removing step." Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 47**

Claim 47 depends from claim 38 and further recites that "the removing step includes opening a lock to enable access to a storage location."

As previously discussed, Pearson '232 does not disclose the recited dispenser device. It follows that Pearson '232 does not disclose the recited "removing step." It further follows that Pearson '232 does not disclose "opening a lock to enable access to a storage location" in the "removing step." Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 48**

Claim 48 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites "removing at least one unit of a type medical item from a storage location with a dispenser mechanism."

Appellants respectfully submit that Pearson '232 does not disclose the recited features and relationships. The Action alleges that Pearson '232 discloses the recited "removing" step at col. 5, line 42 to col. 6, line 2, and at col. 5, lines 9-35. However, Pearson '232 does not disclose the recited "removing" step at the indicated sections of Pearson '232. The cited sections refer to a nurse manually removing a medical item using a suction tube (12). Claim 48 recites that it is

the dispenser mechanism which carries out the “removing” of a medical item from its storage location, not a human hand. All of the embodiments in Pearson ‘232 involve a nurse manually removing a medical item from its storage location.

Pearson ‘232 at col. 5, lines 9-11 clearly states “the nurse inserts suction tube 12 into the corresponding orifice tube 24.” That is, in Pearson ‘232 a nurse performs the “removing”, not a mechanism. Pearson ‘232 actually works opposite to the recited invention and requires physical labor on the part of the nurse to remove a medical item from its storage location. Pearson ‘232 lacks a dispenser mechanism.

As previously discussed, it is well known that a mechanism implies mechanical operation, not human hand operation. Thus, a nurse cannot constitute the recited “dispenser mechanism.” Furthermore, the suction tube (12) of Pearson ‘232 is not part of nor does it constitute a dispensing mechanism. Again, in Pearson ‘232 it is the nurse that performs the dispensing. The suction tube (12) alone cannot perform any dispensing. Nor is the suction tube (12) used with a “dispenser mechanism” to perform the removing step.

As previously discussed, Appellants’ disclosure makes clear that the recited “dispenser mechanism” relates to mechanical operation and not human hand operation. Note the previously cited Specification sections.

Furthermore, Appellants’ disclosure states that “The vial dispensing mechanism of the present invention enables the controlled dispense of one vial at a time from the magazine in response to an electrical signal. This assures that only the requested medication is dispensed.” “In addition, the gate members are suitably secure so as to avoid tampering by persons who

might attempt to gain access to the interior of the medicine dispenser 100 through the dispenser drawer 176.” (Specification page 45, lines 6-12). Thus, the recited dispensing mechanism of claim 48 actually prevents access to the medical items by a human hand to prevent tampering. Contrarily, Pearson ‘232 allows access to the pills by hand which could lead to tampering. Thus, the recited invention of claim 48 is an improvement over the Pearson ‘232 reference.

Furthermore, claim 48 step (c) recites “removing at least one unit of a type medical item from a storage location with a dispenser mechanism.” Claim 48 further recites that “the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item.” There is no indication that in Pearson ‘232 “data is modified responsive to the performance of” actually removing a type medical item from a storage location with a dispenser mechanism. There is no indication that in Pearson ‘232 “data is modified” “representative of the dispense of the type medical item.”

Pearson ‘232 is not capable of verifying that a medical item was actually removed with a dispenser mechanism. That is, Pearson ‘232 is not capable of verifying the performance of recited step (c). It follows that Pearson ‘232 is not capable of modifying data representative of the actual dispense of a type medical item (i.e., step (d)).

As previously discussed, in Pearson ‘232 the sensors (42) are used to detect the presence of a pill. Upon the sensor detecting a pill, the computer is then updated to reflect (assumed) removal of a pill in order to keep accurate inventory (col. 5, lines 29-33). However, the sensors (42) only detect whether a pill, while still in the container, has been successfully picked up. The sensors (42) do not verify whether a pill was actually dispensed. Data is not modified to be

“representative of the dispense of the type medical item.” Therefore, inaccurate data may be presented. Thus, the claimed invention is an improvement over the Pearson ‘232 reference.

For example, Pearson ‘232 at col. 6, lines 8-10 indicates that the pill may be accidentally dropped. That is, a pill may be dropped after the pill was detected by the sensors (42). Hence, the detected pill may be dropped (e.g., in the same container) without ever being dispensed or reaching the patient. Thus, Pearson ‘232 is not capable of verifying an actual medical item removal from a storage location with a dispenser mechanism.

Pearson ‘232 does not disclose “modifying data” in a data store responsive to actually removing a type medical item from a dispenser mechanism. That is, Pearson ‘232 does not disclose modifying data indicating that the requested medical item was actually dispensed. Therefore, Pearson ‘232 does not disclose step (c) or (d).

In an exemplary embodiment of the present invention there is a verification that the item actually dispensed is that item that is recorded for that particular patient (Specification page 45, line 13 to page 46, line 2). That is, in the exemplary embodiment the dispense of any item from a location and the provision of such item to a patient is only recorded in the computer data store when the dispense is verified by a sensor (e.g., 179) (Specification page 40, lines 1-3) associated with the magazine. This permits the assurance that the requested medical item has been truly dispensed by the dispenser mechanism. A dispense verification sensor may be used to minimize the risk that a dispense will be recorded which has not actually occurred due to a malfunction. Pearson ‘232 provides no disclosure that a medication has been actually verified as having been dispensed prior to indicating such in a data store. The Pearson ‘232 reference appears

unconcerned about the possibility of inaccurately recording a particular medical item when the item was never actually dispensed. In Pearson '232 the dispensing of a medical item is recorded whether or not it actually occurred. Therefore, the system of Pearson '232 permits medication errors to occur. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed to a user (e.g., nurse). Pearson '232 has none of these advantages. Thus, the invention recited in claim 48 is clearly an improvement over the Pearson '232 reference.

It follows that there is no indication that Pearson '232 is responsive to the completion of the steps (b) and (c) to modify data in the manner recited. Furthermore, there is no indication in Pearson '232 that data is modified to include data representative of the actual "dispense of the type medical item for the patient." Pearson '232 is not directed to having data modified in response to both inputting patient identifying data and dispensing a medical item with a dispenser mechanism. Nor is Pearson '232 directed to modifying a data store data to include data representative that the medical item was actually dispensed for that particular patient.

Furthermore, claim 48 at step (a) refers to different "types" of medical items. Step (c) includes removing a particular "type" of medical item. Step (d) is "responsive to the performance" or completion of step (c). Pearson '232 is not directed to modifying a data store data to include data representative that the medical item was verified as a particular "type" of medical item. Therefore, in an exemplary embodiment of the present invention, not only is data modified representative of the actual dispense of the medical item, but data is also modified

representative that the correct type of medical item was dispensed. That is, not only is a medical item verified as having been dispensed, but the correct type of medical item is verified as having been dispensed (e.g., Specification page 45, line 13 to page 46, line 2). There is no disclosure or suggestion in Pearson ‘232 that a particular “type” of medical item is ever confirmed as actually having been dispensed from a dispenser mechanism.

It follows that Pearson ‘232 does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection. Appellants’ claim patentably distinguishes over the Pearson ‘232 reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 49**

Claim 49 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites “storing data in at least one data store in operative connection with the at least one processor indicating that the at least one of the type medical item has been provided for the patient.”

Appellants respectfully submit that Pearson ‘232 does not disclose the recited features and relationships. The Action alleges that Pearson ‘232 discloses the recited “storing” step at col. 4, lines 60-67. However, Pearson ‘232 does not disclose the recited “storing” step at the indicated section of Pearson ‘232.

The cited section of Pearson ‘232 does not discuss “storing data . . . indicating that the . . . type medical item has been provided for the patient” in the manner recited. Nor does Pearson ‘232 disclose the recited storing step.

Pearson '232 is not capable of verifying that a medical item was actually provided.

Hence, Pearson '232 is not capable of storing data indicating such action.

As previously discussed, in Pearson '232 the sensors (42) are used to detect the presence of a pill. Upon the sensor detecting a pill, the computer is then updated to reflect (assumed) removal of a pill in order to keep accurate inventory (col. 5, lines 29-33). However, the sensors (42) only detect whether a pill, while still in the container, has been successfully picked up. The sensors (42) do not verify whether a pill was actually dispensed. No embodiment of Pearson '232 confirms or verifies that a medical item was actually provided. In Pearson '232, it appears that after the nurse verifies the correct patient information, then the preprogrammed computer unlocks each appropriate container (8) or drawer (10) and automatically updates the records to reflect the (assumed) dispensing of a medical item. However, there is no verification of such assumed dispensing. Hence, in Pearson '232 data is not stored indicating that a medical item was actually provided.

For example, Pearson '232 at col. 6, lines 8-10 indicates that the pill may be accidentally dropped. That is, a pill may be dropped after the pill was detected by the sensors (42). Hence, the detected pill may be dropped (e.g., in the same container) without ever being dispensed or reaching the patient. Thus, Pearson '232 is not capable of verifying an actual medical item removal from a storage location with a dispenser mechanism. Therefore, inaccurate data may be presented. Thus, the claimed invention is an improvement over the Pearson '232 reference.

Pearson '232 does not disclose storing data in a data store indicating that the medical item has been provided for the patient. Therefore, the system of Pearson '232 permits medication



errors to occur. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed. Thus, the invention recited in claim 49 is clearly an improvement over the Pearson '232 reference.

Furthermore, claim 49 at step (d) refers to “inputting medical item data corresponding to a type medical item.” Step (f) includes “storing data . . . indicating that the at least one of the type medical item has been provided.” Therefore, the system of the present invention not only includes “indicating” (verifying) that a “medical item has been provided” (dispensed) from the storage device (e.g., dispenser mechanism), but it also verifies that the correct type of inputted medical item was provided (dispensed). That is, not only is a medication item verified as having been dispensed, but the correct type of medical item is verified as having been dispensed (e.g., Specification page 45, line 13 to page 46, line 2). Pearson '232 is not directed to verifying that a medication item was dispensed. It follows that Pearson '232 is not directed to verifying that a correct “type” of medication item was dispensed. Thus, Pearson '232 does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection.

It follows that Pearson '232 does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection. Appellants' claim patentably distinguishes over the Pearson '232 reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **Claim 50**

Claim 50 depends from claim 49 and further recites “dispensing the at least one of the type medical item from a dispenser device.” That is, the storage device includes a dispenser device. Access to a type medical item is provided by the dispensing of the type medical item from the dispenser device.

As previously discussed, Pearson ‘232 does not disclose “dispensing” using a “dispenser device” in the manner recited. In Pearson ‘232 the medical items are removed by hand. The medical items are not dispensed from a dispenser device (e.g., dispenser mechanism). Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **Claim 51**

Claim 51 depends from claim 49 and further recites “unlocking a drawer to enable access to the at least one of the type medical item.”

Pearson ‘232 does not disclose the recited features and relationships in the manner recited. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **Claim 52**

Claim 52 depends from claim 49 and further recites “releasing the at least one of the type medical item from a device holding such type item.”

Pearson ‘232 does not disclose the recited “releasing” of a medical item from a device holding the medical item in the manner recited. Pearson ‘232 does not disclose a holding device capable of releasing a medical item. In Pearson ‘232 a nurse simply reaches into a drawer (10) to

take a medical item. Pearson '232 does not disclose an embodiment where a medical item is released in the manner recited. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

**Claim 53**

Claim 53 depends from claim 49 and further recites opening a lock to enable access to the storage location.

Pearson '232 does not disclose the recited features and relationships in the manner recited. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

**The Pending Claims Are Not Anticipated By Pearson '029**

Claims 48-53 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Pearson '029.

These rejections are respectfully traversed. Appellants traverse these rejections on the grounds that the Pearson '029 reference does not contain all the elements of the claimed invention arranged in the manner recited in the claims. The features recited in Appellants' claims patentably distinguish over the Pearson '029 reference.

**Claim 48**

Claim 48 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites "modifying data in at least one data store through operation of at least one processor, wherein the at least one processor is in

operative connection with the at least one data store, the data entry device and the dispenser mechanism, wherein the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient.”

Appellants respectfully submit that Pearson ‘029 does not disclose the recited features and relationships. Pearson ‘029 does not disclose “modifying data in at least one data store.” Pearson ‘029 does not disclose “modifying data” through the operation of a processor in operative connection with a dispenser mechanism. Nor does Pearson ‘029 disclose “modifying data” through the operation of at least one processor that is in operative connection with “the at least one data store, the data entry device and the dispenser mechanism.”

There is no indication that Pearson ‘029 includes a “data store.”

There is no indication that Pearson ‘029 includes “modifying data in at least one data store.” The Action alleges that Pearson ‘029 discloses “modifying data” at col. 5, lines 32-46. However, this noted section of Pearson ‘029 does not discuss any modification of data.

At best, Pearson ‘029 may record data (col. 2, lines 29-36) (probably for later printout). However, this data is taken from the previously loaded (unaltered) data already in the software program. The only addition to this data may be the time that the predetermined medication was dispensed. In Pearson ‘029 there is no indication that data in an existing data store is modified or updated. It appears that any data recorded is a newly created one time file, without any “modifying” of data already in an existing data store.

In an exemplary embodiment of the present invention the patient’s file in the data store is updated upon dispensing medication for that particular patient. For example, Appellants’

Specification at page 6, line 14 to page 7, line 5 indicates that the data store includes records concerning patients, procedures, authorized users of the system, and each of the products stored in each of the locations, including pricing information. The user, such as a nurse, uses the interface of the data terminal to identify the particular patient who is to receive the medical items taken by the user. Upon removal of the items from the storage locations, the use of such items is recorded in the respective patient record in the data store so that the patient's chart may be automatically updated and the item charged.

Furthermore, in an exemplary embodiment, the dispense of any item from a location and the provision of such item to a patient is only recorded in the computer data store when the dispense is verified by the sensor associated with the magazine (Specification page 45, lines 13-20). Thus, in the invention recited in claim 48 it is an existing file that is modified or updated. In other words, there has to be an existing data store before the data store can be modified. There is no indication that this is the situation in Pearson '029. Pearson '029 does not disclose "modifying data" "to include data representative of the dispense of the type medical item for the patient." At best Pearson '029 creates a new file for the newly recorded data.

There is no indication that Pearson '029 includes "modifying data" in a data store through the operation of a processor in operative connection with the data store to include data representative of the dispense of the type medical item for the patient. It follows that Pearson '029 does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection. Hence, Appellants'

claim patentably distinguishes over the Pearson '029 reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 49**

Claim 49 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites “determining through operation of at least one processor that the user identifying data input in step (a) corresponds to authorized user data in at least one data store that is in operative connection with the at least one processor.” The claim further specifically recites “storing data in at least one data store in operative connection with the at least one processor indicating that the at least one of the type medical item has been provided for the patient.”

Appellants respectfully submit that Pearson '029 does not disclose the recited features and relationships. Pearson '029 does not disclose determining that the user is an authorized user. Nor does Pearson '029 disclose that the user is provided access to a type medical item in response to inputting medical item data through the input device.

The Action alleges that Pearson '029 discloses determining an authorized user at col. 5, lines 14-21. The Appellants disagree with the allegation. The cited section of Pearson '029 does not discuss that the user is an “authorized user.” The cited section indicates that the nurse (user) merely inputs the patient's ID into the keyboard, then the computer, based on the predetermining software, energizes a light corresponding to the outlet location of the medication for that particular patient. Pearson '029 does not disclose inputting a user ID. Pearson '029 does not disclose corresponding (comparing) inputted user ID to stored authorized user data. The

invention in claim 49 permits only an authorized user access to dispense medication. There is no disclosure that this is the situation in Pearson '029. Thus, the present invention is an improvement over the Pearson '029 reference.

It is noted that Pearson '029 does mention “authorized” personnel at col. 2, lines 58-63. However, the mentioned “authorized” personnel refers only to the personnel authorized to load the software program into the computer, not the user. It is the nurse who is the user or operator. Therefore, Pearson '029 does not disclose determining that the user is an authorized user. Hence, Pearson '029 does not anticipate the claim.

Pearson '029 also does not disclose storing data in a data store indicating that the medical item has been provided for the patient. That is, Pearson '029 does not disclose storing data indicating that the requested medical item was actually dispensed. As previously discussed, in an exemplary embodiment of the invention, the dispense of any item from a location and the provision of such item to a patient is only recorded in the computer data store when the dispense is verified by the sensor associated with the magazine (Specification page 45, lines 18-20). Pearson '029 provides no disclosure that a medication has been actually verified as having been dispensed prior to indicating such in a data store. Thus, Pearson '029 does not meet the recited features and relationships of step (f).

The Action alleges that Pearson '029 discloses storing data indicating that the medical item has been provided for the patient at col. 2, lines 29-56. The Appellants disagree with the allegation. Pearson '029 does not disclose verifying or indicating that the requested medical item

was actually ever dispensed. That is, Pearson '029 does not verify that the requested medical item was "provided." Nor does Pearson '029 store data relating to the indication.

In Pearson '029 it is the nurse that "verifies that there is no mistake in the medication dispensed by comparing" (col. 5, lines 47-53). However, there is no "storing" of this nurse's personal information in a data store. In Pearson '029 the dispensing of a medical item appears to be recorded whether or not it actually occurred. This is because the predetermined software acts on its own once the patient ID is entered (col. 5, lines 16-21). Therefore, the system of Pearson '029 permits medication errors to occur. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed to a user (e.g., nurse). Pearson '029 has none of these advantages. Thus, the present invention is an improvement over the Pearson '029 reference. Pearson '029 does not disclose storing data in a data store indicating that the medical item has been provided for the patient. Hence, Pearson '029 does not anticipate the claim.

It follows that Pearson '029 does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection. Hence, Appellants' claim patentably distinguishes over the Pearson '029 reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn. It is therefore respectfully submitted that the claim as well as claims 50-53 which depend therefrom are allowable.



### **Claim 50**

Claim 50 depends from claim 49 and further recites “dispensing the at least one of the type medical item from a dispenser device.”

As previously discussed, Pearson ‘029 does not disclose determining an authorized user. Nor does Pearson ‘029 disclose the recited “storing data.” It follows that Pearson ‘029 does not disclose the recited “dispensing” of claim 50. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **Claim 51**

Claim 51 depends from claim 49 and further recites “unlocking a drawer to enable access to the at least one of the type medical item.”

The Action is silent as to where Pearson ‘029 discloses the recited “unlocking a drawer” in the U.S.C. § 102(e) rejection. Nor is it seen where Pearson ‘029 discloses the recited “unlocking a drawer to enable access to the at least one of the type medical item.”

Furthermore, Pearson ‘029 has been solely applied in a 35 U.S.C. § 103(a) rejection of claim 51 (Action page 8). Hence, by inference claim 51 is not anticipated by Pearson ‘029.

It follows that Pearson ‘029 does not disclose the recited features of claim 51. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **Claim 52**

Claim 52 depends from claim 49 and further recites “releasing the at least one of the type medical item from a device holding such type item.”

Pearson '029 does not disclose the recited "releasing" of a medical item from a device holding the item. In Pearson '029 a tablet is lifted (col. 5, line 6) from a container (37). It follows that Pearson '029 does not disclose the recited "releasing." Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **Claim 53**

Claim 53 depends from claim 49 and further recites opening a lock to enable access to the storage location.

The Action is silent as to where Pearson '029 discloses opening a lock in the U.S.C. § 102(e) rejection. Nor is it seen where Pearson '029 discloses the recited "opening the at least one lock to enable access to the storage location."

Furthermore, Pearson '029 has been solely applied in a 35 U.S.C. § 103(a) rejection of claim 53 (Action page 8). Hence, by inference claim 53 is not anticipated by Pearson '029.

It follows that Pearson '029 does not disclose the recited features of claim 53. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

### **The Pending Claims Are Not Anticipated By Halvorson**

Claims 48-53 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Halvorson.

These rejections are respectfully traversed. Appellants traverse these rejections on the grounds that the Halvorson reference does not contain all the elements of the claimed invention

arranged in the manner recited in the claims. The features recited in Appellants' claims patentably distinguish over the Halvorson reference.

Furthermore, Halvorson has been solely applied in a 35 U.S.C. § 103(a) rejection of claims 48-53 (Action pages 8-10). Hence, by inference claims 48-53 are not anticipated by Halvorson. Thus, the 35 U.S.C. § 102(e) rejections should be withdrawn.

**Claim 48**

Claim 48 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites in step (b) "inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient."

However, the Action on page 10, lines 1-6, admits that Halvorson does not disclose "inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient." Therefore, Appellants respectfully submit that Halvorson, by the Office's own admission, does not anticipate claim 48. Thus, the 35 U.S.C. § 102(e) rejection should be withdrawn.

Claim 48 also specifically recites "modifying data in at least one data store through operation of at least one processor, wherein the at least one processor is in operative connection with the at least one data store, the data entry device and the dispenser mechanism, wherein the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient."

Appellants respectfully submit that Halvorson does not disclose the recited features and relationships. Halvorson does not disclose that “the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient.”

The Action is silent in the 102(e) rejection as to where Halvorson teaches the recited steps. However, it is noted that the Action later (on page 9) alleges that Halvorson discloses that “the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient” at col. 5, lines 3-25. The Appellants disagree with the allegation. The cited section of Halvorson does not discuss that data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient. The cited section merely indicates that a nurse may request a package from the system (presumably by requesting that the pharmacy program the system to dispense the item). If the item is not already in the dispenser then the nurse will be notified that the pharmacy has ordered the item.

Claim 48 step (b) recites “inputting patient identifying data through at least one data entry device.” Claim 48 step (c) recites “removing at least one unit of a type medical item from a storage location with a dispenser mechanism.” Claim 48 further recites that “the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item.” There is no indication that Halvorson determines or verifies the completion of steps (b) and (c). That is, there is no indication that in Halvorson “data is modified responsive to the performance of” actually removing a type medical item with a

dispenser mechanism. There is no indication that in Halvorson “data is modified”

“representative of the dispense of the type medical item.” Halvorson is not capable of verifying that a medical item was actually removed from a dispenser mechanism. That is, Halvorson is not capable of verifying the performance of recited step (c). It follows that Halvorson is not capable of modifying data representative of the actual dispense of a type medical item (i.e., step (d)).

Halvorson does not disclose “modifying data” in a data store responsive to actually removing a type medical item from a dispenser mechanism. That is, Halvorson does not disclose modifying data indicating that the requested medical item was actually dispensed. Hence, Halvorson does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection.

As previously discussed, in an exemplary embodiment of the present invention there is a verification that the item actually dispensed is that item that is recorded for that particular patient (Specification page 45, line 13 to page 46, line 2). That is, in the exemplary embodiment the dispense of any item from a location and the provision of such item to a patient is only recorded in the computer data store when the dispense is verified by a sensor (e.g., 179) (Specification page 40, lines 1-3) associated with the magazine. This permits the assurance that the requested medical item has been truly dispensed by the dispenser mechanism. A dispense verification sensor may be used to minimize the risk that a dispense will be recorded which has not actually occurred due to a malfunction. Halvorson provides no disclosure that a medication has been actually verified as having been dispensed prior to indicating such in a data store. The Halvorson reference appears unconcerned about the possibility of inaccurately recording a particular

medical item to a patient when the item was never actually dispensed. In Halvorson the dispensing of a medical item is recorded whether or not it actually occurred. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed to a user (e.g., nurse).

The system of the present invention enables accurate recording of a particular medical item to a patient. The system of the present invention also enables accurately identifying activities conducted by users of the system, including identification of possible improprieties or patterns of abuse by users. In the system of Halvorson a nurse can review a list of the medications for a patient that are supposed to be automatically dispensed from the mechanical dispenser at that hour in accordance with the programming of the system by the pharmacy (col. 4, lines 56-60). As each medication in Halvorson is “dispensed” (in the view of the computer because the system sent a signal to the dispenser to do so at the programmed time) a record is automatically appended to the patient’s journal that indicates the patient’s use of that medication (col. 20, lines 28-33; col. 12, lines 62-68). Therefore, the system of Halvorson permits medication errors to occur due to a dispenser mechanism malfunction. That is, in Halvorson a doctor (or any other person using the system to review a patient’s journal) can be misled about the actuality of a patient receiving a medication (col. 6, lines 24-29; col. 9, lines 36-50). In contrast, the system of the present invention specifically takes into consideration the possibility of a dispenser mechanism malfunction. Of course it should be understood that the system of the present invention can also protect a nurse from allegations of theft, for example when a medical

item remains stuck in the dispenser mechanism because of a dispenser mechanism malfunction. Halvorson has none of these advantages. Thus, the invention recited in claim 48 is clearly an improvement over the Halvorson reference.

It follows that there is no indication that Halvorson is responsive to the completion of the steps (b) and (c) to modify data in the manner recited. Furthermore, there is no indication in Halvorson that data is modified to include data representative of the actual “dispense of the type medical item for the patient.” Halvorson is not directed to having data modified in response to both inputting patient identifying data and dispensing a medical item with a dispenser mechanism. Nor is Halvorson directed to modifying a data store data to include data representative that the medical item was actually dispensed for that particular patient.

Furthermore, claim 48 at step (a) refers to different “types” of medical items. Step (c) includes removing a particular “type” of medical item. Step (d) is “responsive to the performance” or completion of step (c). Halvorson is not directed to modifying a data store data to include data representative that the medical item was verified as a particular “type” of medical item. There is no indication in Halvorson that a particular “type” of medical item is ever confirmed as actually having been dispensed from a dispenser mechanism. It follows that Halvorson does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection.

Appellants’ claim patentably distinguishes over the Halvorson reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 49**

Claim 49 is an independent claim which is specifically directed to a method for tracking and dispensing medical items. The claim specifically recites “inputting patient identifying data through at least one input device in operative connection with the at least one processor, wherein the patient identifying data corresponds to a patient.”

However, the Action on page 10, lines 1-6, admits that Halvorson does not disclose “inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient.” Therefore, Appellants respectfully submit that Halvorson, by the Office’s own admission, does not anticipate claim 49. Thus, the 35 U.S.C. § 102(e) rejection should be withdrawn.

Claim 49 also specifically recites “determining through operation of at least one processor that the user identifying data input in step (a) corresponds to authorized user data.” The claim further recites “providing access to at least one of the type medical item to the user from a storage device responsive to performance of at least one of steps (b) and (d).” The claim further recites “storing data in at least one data store in operative connection with the at least one processor indicating that the at least one of the type medical item has been provided for the patient.”

Appellants respectfully submit that Halvorson does not disclose the recited features and relationships. Halvorson does not disclose the steps of “determining . . . that the user identifying data . . . corresponds to authorized user data” and “providing access to at least one of the type



medical item to the user from a storage device” and “storing data . . . indicating that the . . . type medical item has been provided for the patient.”

The Action is silent in the 102(e) rejection as to where Halvorson teaches the recited steps. However, it is noted that the Action later (on page 9) alleges that Halvorson discloses “storing data in at least one data store in operative connection with the at least one processor indicating that the at least one of the type medical item has been provided for the patient” at col. 5, lines 31-66. The Appellants disagree with the allegation. The cited section of Halvorson does not discuss “storing data . . . indicating that the . . . type medical item has been provided for the patient” in the manner recited. The cited section of Halvorson discusses a system operation without a mechanical dispenser. Note the upper left section of Figure 1. The cited operation of dispensing uses a floor cart. A nurse in the cited operation of Halvorson simply takes an item from the cart. The cart is not a storage device interrelated with the host computer. A nurse has no need to input data in relation to taking a medical item from the freely accessible cart. In order to take a medical item from the cart in Halvorson, the computer has no need to determine whether a nurse’s identifying data corresponds to an authorized user data. Halvorson does not require any authorization of nurse data in order for the nurse to take a medical item from the cart. Nor is there any need to provide access to a type medical item on the (unlocked) floor cart. Nor is there any need to provide access to a type medical item on the floor cart responsive to the performance of another step. It follows that the relied upon section of Halvorson is not directed to “storing data . . . indicating that the . . . type medical item has been provided for the patient.”

Claim 49 is directed to providing access to a type medical item from a storage device responsive to the performance of inputting data, and storing data indicating that the type medical item has been provided. As previously discussed, Halvorson does not indicate or verify that a type medical item has been provided. Appellants' arguments regarding Halvorson and claim 48 are herein incorporated by reference. There is no evidence that Halvorson is concerned with indicating that a type medical item was actually provided from a storage device (e.g., dispenser mechanism). Halvorson is not capable of verifying that a medical item was actually removed (i.e., "has been provided") from a storage device. It follows that there is no evidence that Halvorson stores data (in a data store in operative connection with the processor) indicating that a type medical item was actually provided from a storage device. That is, Halvorson is not capable of performing recited step (f).

Halvorson does not disclose storing data in a data store indicating that the medical item has been provided for the patient. That is, Halvorson does not disclose storing data indicating that the requested medical item was actually dispensed. As previously discussed, in an exemplary embodiment of the invention, the dispense of any item from a location and the provision of such item to a patient is only recorded in the computer data store when the dispense is verified by a sensor (e.g., 179) associated with the magazine (Specification page 45, lines 18-20). Halvorson provides no disclosure that a medication has been actually verified as having been dispensed prior to indicating such in a data store.

The Halvorson reference appears unconcerned about the possibility of inaccurately recording a particular medical item to a patient when the item was never actually dispensed (e.g.,

stuck in the dispenser). In Halvorson the dispensing of a medical item is recorded whether or not it actually occurred. In the system of Halvorson a nurse can review a list of the medications for a patient that are supposed to be automatically dispensed from the mechanical dispenser at that hour in accordance with the programming of the system by the pharmacy (col. 4, lines 56-60). As each medication in Halvorson is “dispensed” (in the view of the computer because the system sent a signal to the dispenser to do so at the programmed time) a record is automatically appended to the patient’s journal that indicates the patient’s use of that medication (col. 20, lines 28-33; col. 12, lines 62-68). Therefore, the system of Halvorson permits medication errors to occur due to a dispenser mechanism malfunction. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed. Thus, the invention recited in claim 49 is clearly an improvement over the Halvorson reference. It follows that Halvorson does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection.

Furthermore, there is no indication in Halvorson of “providing access to at least one of the type medical item to the user from a storage device responsive to” “determining through operation of at least one processor that the user identifying data input in step (a) corresponds to authorized user data.” That is, Halvorson does not link the use of corresponding “authorized user data” with “providing access to” (dispensing of) medical items in a storage device. It follows that Halvorson does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection.

Claim 49 at step (d) refers to “inputting medical item data corresponding to a type medical item.” Step (f) includes “storing data . . . indicating that the at least one of the type medical item has been provided.” Therefore, the system of the present invention not only includes “indicating” (verifying) that a “medical item has been provided” (dispensed) from the storage device (e.g., dispenser mechanism), but it also verifies that the correct type of inputted medical item was provided (dispensed). That is, not only is a medication item verified as having been dispensed, but the correct type of medical item is verified as having been dispensed (e.g., Specification page 45, line 13 to page 46, line 2). Halvorson is not directed to verifying that a medication item was dispensed. It follows that Halvorson is not directed to verifying that a correct “type” of medication item was dispensed. Thus, Halvorson does not disclose each and every feature and relationship of the claimed invention arranged in the manner recited in the claim, as is required to sustain the rejection.

Appellants’ claim patentably distinguishes over the Halvorson reference. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 50**

Claim 50 depends from claim 49 and further recites “dispensing the at least one of the type medical item from a dispenser device.” That is, the storage device includes a dispenser device. Access to a type medical item is provided by the dispensing of the type medical item from the dispenser device.

Halvorson does not disclose dispensing using a dispenser device in the manner recited. Furthermore, as previously discussed, Halvorson lacks the recited step of storing data (step e). Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 51**

Claim 51 depends from claim 49 and further recites “unlocking a drawer to enable access to the at least one of the type medical item.”

The Action is silent as to where Halvorson discloses the recited “unlocking a drawer.” Nor is it seen where Halvorson discloses the recited “unlocking a drawer to enable access to the at least one of the type medical item.”

Furthermore, the Action on page 10, lines 7-10, admits that Halvorson does not disclose “unlocking a drawer to enable access to the at least one of the type medical item.” Therefore, Appellants respectfully submit that Halvorson, by the Office’s own admission, does not anticipate claim 51. Thus, the 35 U.S.C. § 102(e) rejection should be withdrawn.

Furthermore, even if it were somehow possible for Halvorson to unlock a drawer to enable access to a medical item, Halvorson would still lack evidence of providing (responsive to other steps) the user access to a medical item from (already in) a storage device (claim 49, step e).

In Halvorson spiral members (50) can be rotated to dispense (drop) a unit dose package (col. 3, lines 37-40). Halvorson is silent as to where the user (nurse) picks up the dropped dose package. However, there is no indication that Halvorson permits the user (nurse) access to the

spiral members (50) (the medical item storage location). Additionally, it would appear that security would be in place to prevent a nurse access to the medical item storage locations (50).

It follows that Halvorson does not disclose the recited features of claim 51. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 52**

Claim 52 depends from claim 49 and further recites “releasing the at least one of the type medical item from a device holding such type item.”

Halvorson does not disclose the recited “releasing” of a medical item from a device holding the medical item in the manner recited. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

#### **Claim 53**

Claim 53 depends from claim 49 and further recites opening a lock to enable access to the storage location.

The Action is silent as to where Halvorson discloses opening a lock. Nor is it seen where Halvorson discloses opening a lock to enable access to a storage location of the storage device.

Furthermore, even if it were somehow possible for Halvorson open a lock to enable access to a medical item storage location, Halvorson would still lack evidence of providing (responsive to other steps) “the user” access to a medical item storage location of a storage device (claim 49, step e).

In Halvorson, spiral members (50) can be rotated to dispense (drop) a unit dose package (col. 3, lines 37-40). Halvorson is silent as to where the user (nurse) picks up the dropped dose

package. However, there is no indication that Halvorson permits the user (nurse) access to the spiral members (50) (the medical item storage location). Additionally, it would appear that security would be in place to prevent a nurse direct access to the medical item storage locations (50).

It follows that Halvorson does not disclose the recited features of claim 53. Therefore, it is respectfully submitted that the 35 U.S.C. § 102(e) rejection should be withdrawn.

**(iv) 35 U.S.C. § 103**

**The Pending Claims Are Not Obvious Over  
Pearson ‘232 in View of Meador**

Claims 39-43, 45-47, and 49-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Pearson ‘232 in view of Meador.

Appellants’ previous arguments why these claims patentably distinguishes over the Pearson ‘232 reference are herein incorporated by reference.

Meador has only been applied to allegedly teach “receiving data read from an object.” However, “receiving data read from an object” only appears in claim 42. Therefore, it appears that Meador has only been applied against claim 42.

**Claims 39-43 and 45-47**

The Action on page 10 admits that the Declaration was effective in overcoming the rejections relying upon the Meador reference with respect to claims 38 and 48. However, claims

39-43 and 45-47 depend from claim 38. Hence, it follows that Meador is not prior art against claims 38-43 and 45-47. Again, Pearson '232 is also not prior art. Therefore, claims 39-43 and 45-47 overcome the rejection of Pearson '232 in view of Meador.

#### **Claim 42**

The Action admits that Pearson '232 lacks "receiving data read from an object." Meador has only been applied to allegedly teach "receiving data read from an object." Therefore, it appears that Meador is only applied against claim 42 which contains said language. However, the cited section (col. 5, lines 12-25) of Meador is not directed to "receiving data read from an object." It is respectfully submitted that Meador does not teach "receiving data read from an object" in the manner recited. Hence, it would not have been obvious to have combined Meador with Pearson '232. Furthermore, even if the teachings of Meador were combined with the teachings of Pearson '232 the recited invention would still not have been produced. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

#### **Claims 49-53**

As previously discussed, Pearson '232 lacks numerous recited steps, features, and relationships with regard to claim 49-53.

Meador cannot overcome the deficiencies of Pearson '232 as it does not disclose or suggest the recited features which are not found in Pearson '232. The Action is silent as to how Pearson '232 could be modified by Meador to include the recited features and relationships. The Action is devoid of any such teaching, suggestion, or motivation for combining the references.



Neither Pearson '232 nor Meador alone or in combination disclose or suggest the features and relationships that are specifically recited in the claim.

The Action does not state in any way that is reasonably understandable by Appellants, where the elements recited in Appellants' claims are allegedly found in the cited art. Nor is there any citation to any alleged teaching, suggestion, or motivation to combine features of the prior art to produce the invention as claimed by Appellants. For this reason it is respectfully submitted that the Action fails to establish a prima facie case of obviousness against any of the claims and the rejection should be withdrawn.

Because the Action fails to apply the references to the claims, Appellants have been required to speculate as to possible rationales for the rejections. Appellants have reviewed the references cited and have determined that the cited references, taken individually or as a whole, clearly do not teach or suggest the invention recited in Appellants' claims. Therefore, the claims would not have been obvious to one having ordinary skill in the art.

It follows that claims 49-53 patentably distinguish over Pearson '232 in view of Meador. It is respectfully submitted that the 35 U.S.C. § 103(a) rejections should be withdrawn.

**The Pending Claims Are Not Obvious Over  
Pearson '232 in View of Blechl**

Claims 38-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Pearson '232 in view of Blechl.

Appellants' previous arguments why these claims patentably distinguishes over the Pearson '232 reference are herein incorporated by reference. Likewise, Appellants' previous arguments that Pearson '232 does not constitute prior art are reiterated as if fully restated herein.

Blechl has only been applied to allegedly teach "displaying and entering data via a touch screen" (col. 4, lines 20-38) and "receiving data read from an object" (col. 4, lines 3-19). However, a "touch screen" only appears in claim 44, and "receiving data read from an object" only appears in claim 42. Therefore, it appears that Blechl has only been applied against claims 42 and 44.

As previously discussed, Pearson '232 lacks numerous recited steps, features, and relationships in regard to the other claims 38-41, 43, and 45-53.

Blechl cannot overcome the deficiencies of Pearson '232 as it does not disclose or suggest the recited features which are not found in Pearson '232. The Action is silent as to how Pearson '232 could be modified by Blechl to include the recited features and relationships. The Action is devoid of any citation to a prior art teaching, suggestion, or motivation for combining the references. Neither Pearson '232 nor Blechl alone or in combination disclose or suggest the features and relationships that are specifically recited in the claim.

The Action does not state in any way that is reasonably understandable by Appellants, where the elements recited in Appellants' claims 38-41, 43, and 45-53 are allegedly found in the cited art. Nor is there any citation to any alleged teaching, suggestion, or motivation to combine features of the prior art to produce the invention as claimed by Appellants. For this reason it is

respectfully submitted that the Action fails to establish a prima facie case of obviousness against any of the claims and the rejection should be withdrawn.

Because the Action fails to apply the references to the claims, Appellants have been required to speculate as to possible rationales for the rejections. Appellants have reviewed the references cited and have determined that the cited references, taken individually or as a whole, clearly do not teach or suggest the invention recited in Appellants' claims. Therefore, the claim would not have been obvious to one having ordinary skill in the art.

#### **Claim 42**

The Action admits that Pearson '232 lacks "receiving data read from an object." The cited section (col. 4, lines 3-19) of Blechl refers to an identification card and a card reader (32). The Action merely states that "It would have been obvious to read data from an object as taught by Blechl." The Appellants disagree. The Action has provided no citation to any teaching, suggestion, or motivation to combine the card and card reader features of Blechl with the teaching of Pearson '232.

Furthermore, the system of Pearson '232 enjoys the simplicity of only requiring a nurse to input a password. It is respectfully submitted that it would not have been obvious to have modified Pearson '232 to include an unnecessary and costly card and card reader arrangement. Also, it would appear that such a modification would destroy the intended operability of the Pearson '232 device.

A reference teaching away from the recited invention does not support prima facie obviousness. It is improper to reconstruct the invention from the disclosure of the Appellants.

An obviousness rejection cannot be based on a combination of features in references if making the combination would result in destroying the utility or advantage of the device shown in the prior art references. *In re Fine*, 5 USPQ2d 1598-99 (Fed. Cir. 1988). As the combination of features asserted in the Action would destroy the utility and advantages of the cited reference it is respectfully submitted that the rejection is improper and should be withdrawn.

Hence, it would not have been obvious to have combined Blechl with Pearson '232. Furthermore, even if the teachings of Blechl were combined with the teachings of Pearson '232 the recited invention would still not have been produced. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

#### **Claim 44**

The Action admits that Pearson '232 lacks “displaying and entering data via a touch screen.” The cited section (col. 4, lines 20-38) of Blechl refers to a touch screen (30). The Action states that “It would have been obvious to display and enter data via a touch screen.” The Appellants disagree.

It would not have been obvious to have combined Blechl with Pearson '232. Furthermore, even if the teachings of Blechl were combined with the teachings of Pearson '232 the recited invention would still not have been produced. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

### **The Pending Claims Are Not Obvious Over Pearson '029**

Claims 48-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Pearson '029. These rejections are respectfully traversed.

Appellants traverse these rejections on the grounds that Appellants' claims recite features which are neither disclosed nor suggested in the prior art, and because there is no teaching, suggestion, or motivation cited so as to produce Appellants' invention. The features recited in Appellants' claims patentably distinguish over the applied reference.

The 35 U.S.C. § 103(a) rejections involving Pearson '029 only refer to claims 51 and 53. Appellants' previous arguments why claims 48-53 patentably distinguish over the Pearson '029 reference and the 35 U.S.C. § 102(e) rejections are herein incorporated by reference.

#### **Claim 51**

Claim 51 depends from claim 49 and further recites "unlocking a drawer to enable access to the at least one of the type medical item."

The Action alleges that Pearson '029 discloses "unlocking a drawer to enable access to the at least one of the type medical item" (col. 5, line 64 to col. 6, line 4). The Appellants disagree.

The cited section of Pearson '029 refers to unlocking and locking dispensing devices. However, these devices appear to be a part of a dispenser unit (35) (col. 3, lines 66-68) in a dispenser area XY (col. 3, lines 36-38). The drawers (22) in Pearson '029 are not associated with dispensing nor are they referred to as dispensing devices. Thus, the cited section of Pearson '029 does not refer to a "drawer" as is recited in the claim. A user in Pearson '029 does not have

“access” to a medical item in dispenser area XY. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

**Claim 53**

Claim 53 depends from claim 49 and further recites opening a lock to enable access to the storage location.

The Action alleges that Pearson ‘029 discloses opening a lock to enable access to a storage location. (col. 5, line 64 to col. 6, line 4). The Appellants disagree.

The cited section of Pearson ‘029 refers to unlocking and locking dispensing devices. However, these devices appear to be a part of a dispenser unit (35) (col. 3, lines 66-68) in a dispenser area XY (col. 3, lines 36-38). A user in Pearson ‘029 does not have “access” to a medical item in dispenser area XY. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

**The Pending Claims Are Not Obvious Over Halvorson**

Claims 48-53 were rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Halvorson. These rejections are respectfully traversed.

Appellants traverse these rejections on the grounds that Appellants’ claims recite features which are neither disclosed nor suggested in the prior art, and because there is no teaching, suggestion, or motivation cited so as to produce Appellants’ invention. The features recited in Appellants’ claims patentably distinguish over the applied reference.

Appellants' arguments regarding Halvorson and the 35 U.S.C. § 102(e) rejections of claims 48-53 are herein incorporated by reference.

**Claim 48**

Claim 48 is an independent claim which is specifically directed to a method for tracking and dispensing medical items.

The claim specifically recites "inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient." As previously discussed, the Action on page 10, lines 1-6, admits that Halvorson does not disclose "inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient."

As previously argued, Halvorson also does not disclose that "the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient."

Furthermore, there is no indication that Halvorson determines or verifies the completion of steps (b) and (c). That is, there is no indication that in Halvorson "data is modified responsive to the performance of" actually removing a type medical item from a dispenser mechanism. There is no indication that in Halvorson "data is modified" "representative of the dispense of the type medical item." Halvorson is not capable of verifying that a medical item was actually removed from a dispenser mechanism. That is, Halvorson is not capable of verifying the performance of recited step (c). It follows that Halvorson is not capable of modifying data representative of the actual dispense of a type medical item (i.e., step (d)).

The Halvorson reference appears unconcerned about the possibility of inaccurately recording a particular medical item to a patient when the item was never actually dispensed. In Halvorson the dispensing of a medical item is recorded whether or not it actually occurred. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed to a user (e.g., nurse).

The system of Halvorson permits medication errors to occur due to a dispenser mechanism malfunction. In contrast, the system of the present invention specifically takes into consideration the possibility of a dispenser mechanism malfunction. Thus, the invention recited in claim 48 is clearly an improvement over the Halvorson reference.

Furthermore, Halvorson is not directed to modifying a data store data to include data representative that the medical item was verified as a particular “type” of medical item. There is no indication in Halvorson that a particular “type” of medical item is ever confirmed as actually having been dispensed from a dispenser mechanism.

Halvorson does not disclose or suggest the recited features. The deficiencies in Halvorson have already been discussed in detail in Appellants arguments regarding Halvorson and the 35 U.S.C. § 102(e) rejections of claims 48-53. No other reference(s) has been applied to overcome the deficiencies of Halvorson.

The Action alleges that Halvorson suggests inputting patient identifying data through at least one data entry device. The Appellants disagree.



In the system of Halvorson a nurse can review a list of medications for a patient that are supposed to be automatically dispensed from the mechanical dispenser at that hour in accordance with the programming of the system by the pharmacy (col. 4, lines 56-60). A nurse in Halvorson does not input patient identifying data through a data entry device. Even the Action admits such. Additionally, in Halvorson there is no modifying of data (step d) responsive to the inputting of patient identifying data (step b).

As nothing in the cited art discloses nor suggests the features and relationships that are specifically recited in Appellants' claim, and because there is no teaching, suggestion, or motivation cited for combining or modifying features of the applied reference so as to produce Appellants' invention, it is respectfully submitted that the claim is allowable for these reasons. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn. It is respectfully submitted that all claims that depend therefrom should also be allowed.

#### **Claim 49**

Claim 49 is an independent claim which is specifically directed to a method for tracking and dispensing medical items.

The claim specifically recites "inputting patient identifying data through at least one input device in operative connection with the at least one processor, wherein the patient identifying data corresponds to a patient." As previously discussed, the Action on page 10, lines 1-6, admits that Halvorson does not disclose "inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient."

The Action alleges that Halvorson suggests inputting patient identifying data through at least one data entry device. The Appellants disagree. Note Appellants previous remarks regarding Halvorson and the 35 U.S.C. § 103(a) rejection of claim 48, herein incorporated by reference.

As previously discussed, Halvorson also does not disclose the steps of “determining . . . that the user identifying data . . . corresponds to authorized user data” and “providing access to at least one of the type medical item to the user from a storage device” and “storing data . . . indicating that the . . . type medical item has been provided for the patient.”

Claim 49 is also directed to providing access to a type medical item from a storage device responsive to the performance of inputting data, and storing data indicating that the type medical item has been provided. As previously discussed, Halvorson does not indicate or verify that a type medical item has been provided. Appellants’ arguments regarding Halvorson and claim 48 are also herein incorporated by reference. Halvorson is not capable of verifying that a medical item was actually removed (i.e., “has been provided”) from a storage device. It follows that there is no evidence that Halvorson stores data (in a data store in operative connection with the processor) indicating that a type medical item was actually provided from a storage device. That is, Halvorson is not capable of performing recited step (f).

Halvorson does not disclose storing data in a data store indicating that the medical item has been provided for the patient. That is, Halvorson does not disclose storing data indicating that the requested medical item was actually dispensed. Halvorson provides no disclosure that a

medication has been actually verified as having been dispensed prior to indicating such in a data store.

The Halvorson reference appears unconcerned about the possibility of inaccurately recording a particular medical item to a patient when the item was never actually dispensed. In Halvorson the dispensing of a medical item is recorded whether or not it actually occurred. Whereas the system of the present invention reduces the risk that medical items will be improperly recorded by having the capability of tracking the quantity and type of medical items that are actually dispensed to a user (e.g., nurse).

The system of Halvorson permits medication errors to occur due to a dispenser mechanism malfunction. In contrast, the system of the present invention specifically takes into consideration the possibility of a dispenser mechanism malfunction. Thus, the invention recited in claim 49 is clearly an improvement over the Halvorson reference.

Halvorson also does not link the use of corresponding “authorized user data” with “providing access to” (dispensing of) medical items in a storage device.

Furthermore, Halvorson is not directed to storing data in a data store indicative that the correct “type” medical item was provided. There is no indication in Halvorson that a particular “type” of medical item is ever confirmed as actually having been dispensed. In system of the present invention not only is a medication item verified as having been dispensed, but the correct type of medical item is verified as having been dispensed. Halvorson is not directed to verifying that a medication item was dispensed. It follows that Halvorson is not directed to verifying that a correct “type” of medication item was dispensed.

Halvorson does not disclose or suggest the recited features. The deficiencies in Halvorson have already been discussed in detail in Appellants arguments regarding Halvorson and the 35 U.S.C. § 102(e) rejections of claims 48-53. No other reference(s) has been applied to overcome the deficiencies of Halvorson.

As nothing in the cited art discloses nor suggests the features and relationships that are specifically recited in Appellants' claim, and because there is no teaching, suggestion, or motivation cited for combining features of the applied reference so as to produce Appellants' invention, it is respectfully submitted that the claim is allowable for these reasons. It is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn. It is respectfully submitted that all claims that depend therefrom should also be allowed.

#### **Claim 50**

Claim 50 depends from claim 49 and further recites "dispensing the at least one of the type medical item from a dispenser device." As previously discussed, Halvorson does not disclose or suggest dispensing using a dispenser device in the manner recited. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

#### **Claim 51**

Claim 51 depends from claim 49 and further recites "unlocking a drawer to enable access to the at least one of the type medical item."

The Action is silent as to where Halvorson discloses the recited "unlocking a drawer." Nor is it seen where Halvorson discloses the recited "unlocking a drawer to enable access to the at least one of the type medical item."

Furthermore, the Action on page 10, lines 7-10, admits that Halvorson does not disclose “unlocking a drawer to enable access to the at least one of the type medical item.”

Furthermore, as previously discussed, even if it were somehow possible for Halvorson to unlock a drawer to enable access to a medical item, Halvorson would still lack evidence of providing (responsive to other steps) the user access to a medical item from (already in) a storage device (claim 49, step e). There is no indication that Halvorson permits the user (nurse) access to the spiral members (50) (the medical item storage location). Additionally, it would appear that security would be in place to prevent a nurse direct access to the medical item storage locations (50).

It follows that Halvorson does not disclose or suggest the recited features of claim 51. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

#### **Claim 52**

Claim 52 depends from claim 49 and further recites “releasing the at least one of the type medical item from a device holding such type item.”

As previously discussed, Halvorson does not disclose the recited “releasing” of a medical item from a device holding the medical item in the manner recited. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

#### **Claim 53**

Claim 53 depends from claim 49 and further recites opening a lock to enable access to the storage location.

The Action is silent as to where Halvorson discloses opening a lock. Nor is it seen where Halvorson discloses opening a lock to enable access to a storage location of the storage device.

Furthermore, even if it were somehow possible for Halvorson open a lock to enable access to a medical item storage location, Halvorson would still lack evidence of providing (responsive to other steps) “the user” access to a medical item storage location of a storage device. As previously discussed, there is no indication that Halvorson permits the user (nurse) access to the spiral members (50) (the medical item storage location). Additionally, it would appear that security would be in place to prevent a nurse access to the medical item storage locations (50).

It follows that Halvorson does not disclose or suggest the recited features of claim 53. Therefore, it is respectfully submitted that the 35 U.S.C. § 103(a) rejection should be withdrawn.

### **Other Comments**

All Patent and Trademark Office employees are legally obligated to preserve applications for patents in confidence. 35 U.S.C. § 122 and 18 U.S.C. § 2071 impose statutory requirements which cover the handling of patent applications and related documents. Further note 37 C.F.R. 1.14 and MPEP § 101. Suspension, removal, and even criminal penalties may be imposed for violations of these statutes.

It is respectfully submitted that the Office has violated 35 U.S.C. § 122. Appellants do not take kindly to the mention of confidential information from a confidential patent file that the Office has made available as part of this file at page 10, lines 11-12 of the Action dated

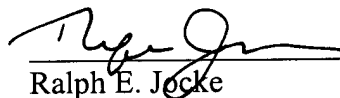
November 16, 2000. This confidential information should remain confidential as required by Federal Law, even if this present application file should later become publicly available.

Appellants request that the Office strike said information from the record, and that proof of such act be presented to Appellants.

### CONCLUSION

As explained above, certain rejections are based on references which do not constitute prior art. In addition, each of the pending claims specifically recite features, relationships, or steps that are neither disclosed nor suggested in any of the applied art. Furthermore, the applied art is devoid of any such teaching, suggestion, or motivation for combining features of the applied art so as to produce Appellant's invention. For these reasons it is respectfully submitted that all the pending claims are allowable.

Respectfully submitted,



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## APPENDIX

### CLAIMS

38. A method for tracking and dispensing medical items comprising the steps of:

placing at least one unit of a plurality of types of medical items in a plurality of storage locations, wherein each storage location holds only one type of medical item at a time;

inputting patient identifying data to a data entry device, wherein the patient identifying data corresponds to a patient;

removing one unit of a type medical item from a storage location with a dispenser mechanism;

modifying a data store using a processor in operative connection with the data store, wherein the processor is in operative connection with the data entry device and the dispenser mechanism, wherein the data store includes data representative of the patient and data representative of the type medical item stored in the storage location, and wherein the data store is modified responsive to the removing step



and the inputting step, to include data representative of the dispense of the type medical item for the patient.

39. The method according to claim 38 and wherein the data store further includes data representative of a plurality of authorized users, and prior to the removing step further comprising the steps of:

receiving user identifying data from a user through a user data entry device;

determining with the processor whether the input user identifying data corresponds to data for an authorized user stored in the data store, wherein the processor operatively controls the dispenser device to enable performance of the removing step only when the input user identifying data corresponds to an authorized user.

40. The method according to claim 39 wherein in the modifying step the data store is further modified to include data representative of a record that the authorized user determined is the determining step dispensed the type medical item.

41. The method according to claim 39 and prior to the removing step further comprising the steps of:

further receiving user identifying data from a further user through the user data entry device; and

further determining with the processor whether the input user identifying data from the further user corresponds to data for an authorized user stored in the data store, other than the authorized user determined in the first determining step, and wherein the removing step is enabled to be performed only when the data received in the receiving and further receiving steps corresponds to two different authorized users.

42. The method according to claim 39 wherein the receiving step includes receiving data read from an object and receiving manually input data.

43. The method according to claim 38 and after the removing step further comprising the step of:

sensing with a verification sensor the dispense of the type medical item removed in the removing step, wherein the verification sensor is in operative connection with the processor, and wherein the modifying step is not performed if the

dispense of the item is not sensed in the sensing step by the verification sensor in the sensing step.

44. The method according to claim 38 wherein the data entry device includes a touch screen, wherein patient identifying indicia is displayed on the touch screen, and wherein the inputting step includes touching the touch screen in an area adjacent the displayed patient identifying indicia.

45. The method according to claim 38 wherein the removing step includes opening an electronic lock drawer.

46. The method according to claim 38 wherein the removing step includes releasing one container from a magazine holding a plurality of containers.

47. The method according to claim 38 wherein the removing step includes opening a lock to enable access to a storage location.

48. A method of tracking and dispensing medical items comprising;

- a) placing at least one unit of a plurality of types of medical items in a plurality of storage locations, wherein each storage location holds only one type of medical item at a time;
- b) inputting patient identifying data through at least one data entry device, wherein the patient identifying data corresponds to a patient;
- c) removing at least one unit of a type medical item from a storage location with a dispenser mechanism;
- d) modifying data in at least one data store through operation of at least one processor, wherein the at least one processor is in operative connection with the at least one data store, the data entry device and the dispenser mechanism, wherein the data is modified responsive to performance of steps (b) and (c) to include data representative of the dispense of the type medical item for the patient.

49. A method for tracking and dispensing medical items comprising;

- a) receiving user identifying data from a user through at least one input device;

- b) determining through operation of at least one processor that the user identifying data input in step (a) corresponds to authorized user data in at least one data store that is in operative connection with the at least one processor;
- c) inputting patient identifying data through at least one input device in operative connection with the at least one processor, wherein the patient identifying data corresponds to a patient;
- d) inputting medical item data corresponding to a type medical item through at least one input device in operative connection with the at least one processor;
- e) providing access to at least one of the type medical item to the user from a storage device responsive to performance of at least one of steps (b) and (d);
- f) storing data in at least one data store in operative connection with the at least one processor indicating that the at least one of the type medical item has been provided for the patient.

50. The method according to claim 49 wherein step (e) includes dispensing the at least one of the type medical item from a dispenser device.

51. The method according to claim 49 wherein step (e) includes unlocking a drawer to enable access to the at least one of the type medical item.

52. The method according to claim 49 wherein step (e) includes releasing the at least one of the type medical item from a device holding such type item.

53. The method according to claim 49 wherein step (e) includes opening the at least one lock to enable access to the storage location.